FEB 17 2000

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

David L. Rose
Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907

Re: Patent Term Extension
Application for
U.S. Patent No. 4,199,569

Dear Mr. Rose:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,199,569 for a period of 1,291 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

Any communication to FDA regarding the patent expiration date in the Orange Book should be directed to Mary Ann Holovac, who will update the Orange Book. Mary Ann's address is

CDEV OIT DDMS
NLRC 235 (HFD-090)
5516 Nicholson Lane
Kensington, MD 20895

A copy of the certificate of extension should also be added to the New Drug Application.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDEV
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: STROMECTOL®
FDA Docket No. 97E-0061

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

PATENT NO.	:	4,199,569
ISSUED	:	April 22, 1980
INVENTOR(S)	:	John C. Chabala et al.
PATENT OWNER	:	Merck & Co., Inc.
PRODUCT	:	STROMECTOL® (ivermectin)

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,291 days

from October 3, 1997, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the Patent and Trademark Office to be affixed this 11th day of February 2000.

Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE
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#22

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Re: STROMECTOL®
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UNDER 35 U.S.C. § 156

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Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

#19

[Federal Register: July 10, 1998 (Volume **63**, Number 132)]
[**Notices**]
[Page 37398-37399]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr10jy98-105]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. 97E-0061]

Determination of Regulatory Review Period for Purposes of Patent Extension; **STROMECTOL**<Register>

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for **STROMECTOL**<Register> and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product **STROMECTOL**<Register> (ivermectin). **STROMECTOL**<Register> is indicated for treatment of strongyloidiasis and onchocerciasis. Subsequent to this approval, the Patent and Trademark Office received a patent term

restoration application for **STROMECTOL**<Register> (U.S. Patent No. 4,199,569) from Merck & Co., Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the

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approval of **STROMECTOL**<Register> represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for **STROMECTOL**<Register> is 2,291 days. Of this time, 2,055 days occurred during the testing phase of the regulatory review period, while 236 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective: August 17, 1990. The applicant claims July 17, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 17, 1990, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the act: April 1, 1996. The applicant claims March 29, 1996, as the date the new drug application (NDA) for **STROMECTOL**<Register> (NDA 50-742) was initially submitted. However, FDA records indicate that NDA 50-742 was submitted on April 1, 1996.

3. The date the application was approved: November 22, 1996. FDA has verified the applicant's claim that NDA 50-742 was approved on November 22, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,026 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 8, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 6, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 1998.
Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.
[FR Doc. 98-18400 Filed 7-9-98; 8:45 am]
BILLING CODE 4160-01-F